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400 Bridle Path Road
Townhouse 43
Bethlehem, PA 18017-3156
March 11, 2001

Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To Whom It May Concern:

Our local blood collection center, The Miller Blood Center in Bethlehem, Pennsylvania has had three crises in three months with insufficient blood supplies to provide to this community's hospitals and to surrounding areas.

I have donated blood in the past. However, on two occasions after being pre-tested, I was told that I had diseases which later proved to be false positives. I then received a letter from the medical director of the center at that time, advising me that never again would the center be permitted to accept my blood, even for plasma, which I had done on numerous occasions. Over the years since that time, I have repeatedly questioned whether or not the FDA rules have changed or expanded to permit me to donate once again, since at no time did I ever have the actual diseases. Their response has consistently been that until and unless the FDA changes the requirements, they may not accept my blood, except in the case of donating for my own use should I require it following surgery or illness.

What is the FDA stance on this ruling at the present? Are there any plans for changing or reexamining the current rules? I am not the only person who questions the accuracy of the blood tests performed on potential donors, but I can only speak for myself.

I will appreciate your response to my questions above.

Sincerely,



(Mrs.) Katherine M. Marinos

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